100, 102, 103, 104, 106, 107, 108, 111, 112, 117, 118, 119, and 121 are amended; claims 109, 110, and 113-116 are canceled, and claims 122-125 are added; as a result, claims 63-108, 111-112, and 117-125 are now pending in this application. Also included in the amended claims are corrected readily apparent typographic errors.

New claims 122-125 are directed to a device, article, or implant of claim 118 which claims embody the elastomer composition of claim 63, and recite: a specific cyclic-flex fatigue resistance (claim 122, page 26, Example 14); and specific degradation resistance rankings (claims 123-125, page 24-26, Example 13 and Table 5). The new claims are supported with analytical and evaluation test data in the specification as filed on the pages indicated.

35 U.S.C. §112 Rejections

Claims 63-121 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The rejection of claims is respectfully traversed and are addressed separately below:

Claim 63 was further amended to indicate "wherein the soft segment includes a compound of formula (I), and a compound selected from the group consisting of a macrodiol, a macrodiamine, and mixtures thereof. The latter clause is believed to be proper Markush group. Thus, the soft segment includes a compound of formula (I), and either or both a macrodiol and a macrodiamine. Additionally, the "a chain extender" in the hard segment can include one or more of the compound of formula (I). Applicants respectfully point out that "a second chain extender" and the last three lines of claim 63 have been deleted to remove any indefiniteness. Thus, claim 63 recites a polyurethane-urea elastomeric composition that includes a soft segment and a hard segment. The hard segment is formed from a diisocyanate and a chain extender of a compound of formula (I). It is understood that the indefinite article "a" in "a chain extender" can mean "one or more" and contemplates additional chain extenders. Additionally, the present amendments are believed to address, remove, and overcome the "mutual exclusivity" issues raised by the Examiner in his remarks on non-responsiveness.

The formula (I) of claims 63, 104, 111, and 112, has been amended to remove

possible confusion. Specifically, formula (I) shows an R_5 bonded directly to the nitrogen atom of the R_5-NH- group.

In claim 111, Applicants have amended the recitation of the soft segment to recite a macrodiol (with species selection in Markush form), or a polyether macrodiamine, or mixtures thereof, and this format is now believed proper:

"the soft segment is formed from:

a macrodiol selected from the group consisting of a polysiloxane macrodiol, a polyether macrodiol, a polyester macrodiol, *and* a polycarbonate macrodiol, *or* a polyether macrodiamine, or mixtures thereof;

Claim 72 was amended to correctly spell "1,3-diaminocyclohexane".

Claims 73 and 74 recite the molar percentage of the compound of formula (I).

Claim 76 deleted "isomer thereof".

In claims 82, 83, 87, and 91, it is respectfully pointed out that PDMS refers to polydimethylsiloxane and as indicated through out the specification as filed, e.g. page 2, line 12. Claims 82, 83, 87, and 91 have been amended accordingly.

In claim 102, the trade name POLAMINE 650 is an amine terminated polytetramethyleneoxide. Claim 102 has been amended accordingly.

In claims 86, 93, 100, 104, 111, and 112, Examiner asserts that the term "about" renders the claims indefinite and states that it cannot be determined exactly which compounds are defined or encompassed by the structure. Although Applicant maintain that the term "about" does not render the claim indefinite, claims 86, 93, 100, 104, 111, and 112 were amended to remove the term "about" in order to facilitate prosecution of the present invention. However, the use of "about" in new claims 122-125 is believed proper and reflect standard deviations or uncertainties in the vales expressed.

Claims 96 and 97 were been amended to reflect the proper dependencies.

Claim 98 was amended to remove the term "based" since "silicon polycarbonate" is itself definite and is further defined by the language in the claim "prepared by reacting an alkylene carbonate with 1,3-bis(4-hydroxybutyl)-1,1,3,3-tetramethyldisiloxane (BHTD)."

In claims 104, 109, and 112, Applicant have amended claim 104 and 112 to remove the allegedly confusing language "a diamine chain extender" as suggested by the Examiner. Applicants canceled 109. Accordingly, the Examiner's objection to second "omissions or matters" in the Examiner's notice of non-compliance is overcome.

Claims 111 and 121 have been amended to correct the typographical errors. Specifically, the relevant semi-colons have been replaced with commas.

In claims 113-117, the Examiner asserts that the terms "resistant," "improved" and "useful as" do not further patentably limit or distinguish the claims. Claims 113-116 have been canceled and claim 117 has been amended such that the term "useful as" has been removed.

Applicant believe claims 63-121 are definite and particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Accordingly, withdrawal of the 35 U.S.C. § 112, second paragraph, rejection is earnestly requested.

Claims 81-103 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make, and/or use the invention. Applicants respectfully traverses this rejection.

Specifically, the Examiner stated that claims 81, 89, 90, 96, and 97 fail to specify the type of molecular weight or how it has been determined. The molecular weights recited in claims 81, 89, 90, 96, and 97 are the number average molecular weights and not the weight average molecular weights. The claims have been amended accordingly. Support for the number average metric for molecular weight is found on page 15, lines 9-14, of the specification as filed "as described by Gunatillake et al.[6] (reference 6 on page 27) and USPatents 5,4039,912" and 5,393,858 (reference page 2, line 26). The foregoing references are incorporated by reference in their entirety. The claims are directed to one of ordinary skill in the art and it would be readily apparent to such a skilled artisan upon review of the specification and the cited references that the number average molecular weight can be readily determined by, for example, size exclusion

chromatography (SEC), see for example, Examples 1, and 7-11 of Applicants' own referenced USPatent 5,4039,912.

Applicants believes that claims 81-103 contain subject matter which is described in such a way as to readily enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

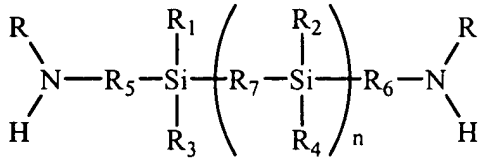
Accordingly, withdrawal of the 35 U.S.C. § 112, first paragraph, rejection is earnestly requested.

35 U.S.C §103 Rejection

Claims 63-121 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Szycher et al. U.S. 5,863,627 (Szycher '627) or WO 98/13405 or JP 4-248826, each in view of Li et al. U.S. 5,221,724 (Li '724) and Ohtaki et al. .S. 5,861,085 (Ohtaki '085). The rejection is respectfully traversed.

Claims 63-108, 111-112, and 117-124

Claim 63 recites a polyurethane-urea elastomeric composition comprising a soft segment and a hard segment, wherein the soft segment is formed from a compound of formula (I):



(I)

and a compound selected from the group consisting of a macrodiol, a macrodiamine, and mixtures thereof;

wherein

R is hydrogen or an optionally substituted straight chain, branched or cyclic,

saturated or unsaturated hydrocarbon radical;

R_1, R_2, R_3, R_4, R_5 and R_6 are each independently hydrogen or an optionally substituted straight chain, branched or cyclic, saturated or unsaturated hydrocarbon radical;

R_7 is a divalent linking group or an optionally substituted straight chain, branched or cyclic, saturated or unsaturated hydrocarbon radical; and

n is an integer of 1 or greater;

wherein the macrodiol is a polysiloxane macrodiol, a polyether macrodiol, a polycarbonate macrodiol, or a mixture thereof;

and wherein the hard segment is formed from:

(i) a diisocyanate; and

(ii) a chain extender comprising the compound of formula (I).

Claim 104 recites a polyurethane-urea elastomeric composition comprising a soft segment and a hard segment, wherein the soft segment is formed from:

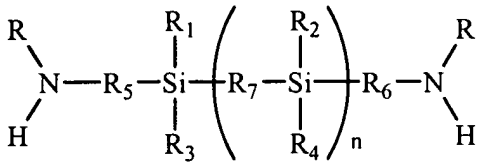
a macrodiol comprising a polysiloxane macrodiol and a polyether macrodiol;

and wherein the hard segment is formed from:

a diisocyanate; and

a chain extender selected from the group consisting of:

a) a compound of formula (I):



(I)

wherein

R is hydrogen or an optionally substituted straight chain, branched or cyclic, saturated or unsaturated hydrocarbon radical;

R_1, R_2, R_3, R_4, R_5 and R_6 are each independently hydrogen or an optionally

substituted straight chain, branched or cyclic, saturated or unsaturated hydrocarbon radical;

R_7 is a divalent linking group or an optionally substituted straight chain, branched or cyclic, saturated or unsaturated hydrocarbon radical; and

n is an integer of 1 to 4;

the molecular weight of the compound of formula (I) is about 500 or less;

b) 1,3-bis(3-aminopropyl)tetramethyldisiloxane;

c) 1,3-bis(4-aminobutyl)tetramethyldisiloxane;

d) 1,4-butanediol;

e) 1,2-ethylenediamine;

f) ethanolamine; hexamethylenediamine;

g) 1,4-butanediamine;

h) water;

i) 1,4-bis(4-hydroxybutyl)tetramethyldisiloxane; and

j) combinations thereof.

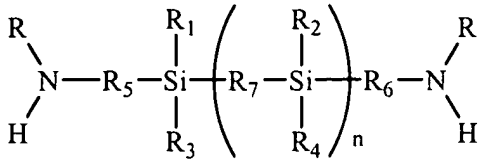
Claim 111 recites a polyurethane-urea elastomeric composition comprising a soft segment and a hard segment, wherein the soft segment is formed from:

a macrodiol selected from the group consisting of a polysiloxane macrodiol, a polyether macrodiol, a polyester macrodiol, and a polycarbonate macrodiol, or a polyether macrodiamine, and mixtures thereof;

and wherein the hard segment is formed from:

a diisocyanate; and

a chain extender comprising a compound of formula (I):



(I)

wherein

R is hydrogen or an optionally substituted straight chain, branched or cyclic, saturated or unsaturated hydrocarbon radical;

R_1, R_2, R_3, R_4, R_5 and R_6 are each independently hydrogen or an optionally substituted straight chain, branched or cyclic, saturated or unsaturated hydrocarbon radical;

R_7 is a divalent linking group or an optionally substituted straight chain, branched or cyclic, saturated or unsaturated hydrocarbon radical; and

n is an integer of 1 to 4; and

wherein the compound of formula (I) has a molecular weight of about 500 or less.

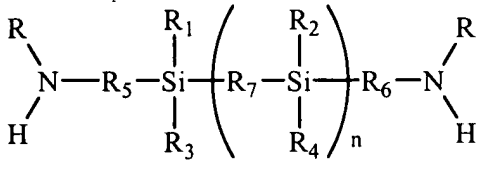
Claim 112 recites a polyurethane-urea elastomeric composition comprising a soft segment and a hard segment, wherein the soft segment is formed from:

a macrodiol comprising a polysiloxane macrodiol and a polycarbonate macrodiol; and the hard segment is formed from:

a diisocyanate; and

a chain extender selected from the group consisting of:

a) a compound of formula (I):



(I)

wherein

R is hydrogen or an optionally substituted straight chain, branched or cyclic, saturated or unsaturated hydrocarbon radical;

R_1, R_2, R_3, R_4, R_5 and R_6 are each independently hydrogen or an optionally

substituted straight chain, branched or cyclic, saturated or unsaturated hydrocarbon radical;

R_7 is a divalent linking group or an optionally substituted straight chain, branched or cyclic, saturated or unsaturated hydrocarbon radical; and

n is an integer of 1 to 4; and

the compound of formula (I) has a molecular weight of about 500 or less;

b) 1,3-bis(3-aminopropyl)tetramethyldisiloxane;

c) 1,3-bis(4-aminobutyl)tetramethyldisiloxane;

d) 1,4-butanediol;

e) 1,2-ethylenediamine;

f) ethanolamine;

g) hexametylenediamine;

h) 1,4-butanediamine;

i) water;

j) 1,4-bis(4-hydroxybutyl)tetramethyldisiloxane; and

k) combinations thereof;

wherein the level of hard segment in the composition is about 21.8 wt.% to about 60 wt.%.

Claim 117 recites a biomaterial that is manufactured from a composition of claim 63.

Claim 118 recites a medical device, article or implant composed wholly or partly of the composition of claim 63.

Claim 120 recites a device or article composed wholly or partly of the composition of claim 63.

The Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the Examiner does not establish a *prima facie* case, the applicant is under no obligation to submit evidence of non-obviousness. M.P.E.P. §2142. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, the prior art reference (or

references when combined) must teach or suggest all the claim elements. Second, there must be some suggestion or motivation in the references or in the knowledge generally available to one of ordinary skill in the art to modify a reference or to combine reference teachings to arrive at the claimed invention. Third, there must be reasonable expectation of success. M.P.E.P. § 2142.

Szycher'627 disclose polycarbonate polyurethanes having internal polysiloxane segments, see the Abstract.

WO 98/13405 The '405 patent discloses a polyurethane elastomeric composition that includes a soft segment derived from at least one polysiloxane macrodiol and at least one polyether and/or polycarbonate macrodiol. The '405 patent, however, does not disclose a silicon diamine of formula (I) as in the present invention.

JP 4-248826 discloses polyurethane and polyurethane-urea polymers comprised of a polyether polyol containing a tertiary-amino or quaternized-amino diol of formula (I) therein, and not a diamine compound of formula (I) as in the present invention.

Li '724 discloses polyurea-urethane and polyurea block copolymers that include an organic diisocyanate-modified amine-terminated polysiloxane of the formula in col. 2, lines 47-54. However, the Li '724 amine-terminated polysiloxane differs from the compound of formula (I) of the present invention particularly with respect to R_7 which can be a divalent linking group (such as O, S, and NR_8 wherein R_8 is hydrogen or an optionally substituted hydrocarbon as disclosed on page 6, lines 26-28) or an optionally substituted straight chain, branched or cyclic, saturated or unsaturated hydrocarbon radical. The Li '724 amine-terminated polysiloxane appears to have a polysiloxane group -(SiR_1R_2O)n- rather than a divalent linker (R_7)of the present invention. Thus the different structure of the amine-terminated polysiloxane of secondary reference Li '724 does not cure the deficiency of any of the primary references to permit one to arrive at the compositions of present invention, i,e, compositions containing compounds of formula (I).

Similarly, Ohtaki '085 discloses amino functional tetraorganodisiloxanes as reactants which compounds also do not cure or complete the deficiency of any of the primary references to permit one to arrive at the compositions of present invention, i,e, compositions containing compounds of formula (I).

The combination of secondary references Li '724 and Ohtaki '085, for the same reasons mentioned above also do not cure or complete the deficiency of any of the primary references.

None of the cited documents {Szycher '627, WO 98/13405, or JP 4-248826; each in view of Li '724 and Ohtaki '085}, alone or in combination, disclose or suggest all of the elements of the presently claimed invention. Specifically, none of these references disclose or suggest the use of a compound of formula (I) as a chain extender as in the present invention. None of these references disclose or suggest polyurethane-urea compositions having a hard segment and a soft segment wherein either or both the hard and soft segments contain a compound of formula (I) as in the present invention. Thus, none of these references, alone or in combination, provide the motivation to combine nor provide any reasonable expectation of success in arriving at the present invention.

It is respectfully submitted that the Examiner has not met the burden of establishing a *prima facie* case of obviousness. Applicant respectfully request withdrawal of the rejection of the present claims under 35 U.S.C. § 103(a).

Conclusion

Applicant respectfully submit that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicants' attorney ((612) 359-3270) to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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Date 8/29/02 By John Haack

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner of Patents, Washington, D.C. 20231, on this 29 day of August, 2002.

Candis B. Buending
Name

Candis Buending
Signature